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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,505	09/28/2001	Steven C. Keith	P-2776P1P1P1	5310
26253	7590	09/09/2004	EXAMINER GITOMER, RALPH J	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,505

Applicant(s)

KEITH, STEVEN C.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Applicant's election without traverse of Group I, claims 1-15, 19-21, in the reply filed on 8/17/04 is acknowledged. Please update the specification regarding the status of related cases. And please inform the examiner as to how the present specification differs from the parent application to confirm the proper priority date for this application based on the first date the claimed material was disclosed. The present abstract is incomplete, please provide a new abstract on a separate page.

This application is a CIP of 09/642,504. The single present inventor does not appear on any of the applications priority is based upon. No priority is granted because there is no common inventor, see MPEP201.11 IV, page 200-63, May 2004. Therefore priority is granted to 9/28/2001. Further searching and or consideration may be required upon resolution of this issue.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bacon.

Bacon (Anal Chem) entitled "Determination of Oxygen Concentrations by Luminescence Quenching of a Polymer Immobilized Transition Metal Complexes" teaches in the abstract, tris(4,7-diphenyl-1, 10-phenanthroline) ruthenium(II) immobilized in a silicone rubber for measuring oxygen concentrations. On page 2780

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column 2, silica gel bound luminescent dye is separated from the solution being measured. On page 2781 column 2, a number of polymers were tried and their qualities discussed. On page 2785 column 1 a silicone rubber matrix is employed to immobilize the ruthenium compound. On page 2781 column 2, calibration curves were experimentally constructed. On page 2783 the Figs. show various plots which are normalized to zero. On page 2784, H₂S acts as an interferent and totally quenches intensity acting as a control.

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Berndt.

Berndt (6,080,574) entitled "Composite Optical Blood Culture Sensor" teaches in column 4 last paragraph, an oxygen sensor with ruthenium compounds. The sensor is for detecting microorganism growth. In column 5 a computer is employed and displays information.

Claims 1-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wodnicka.

Wodnicka (J of Biomolecular Screening) entitled "Novel Fluorescent Technology Platform for High Throughput Cytotoxicity and Proliferation Assays" teaches on page 142, column 1, fluorescence of ruthenium dyes is quenched by oxygen and is used to measure cellular respiration. The dye is immobilized in a silicone matrix.

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All the presently claimed features are taught by the above references for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Parker and Gentle.

Parker (Fiber Optic Sensors) entitled "Chemical Sensors Based on Oxygen Detection by Optical Methods" teaches in the abstract, fluorescence quenching to measure oxygen concentration with 9,10-diphenyl anthracene. On page 156, even when immobilized, fluorescent molecules show a reduction in fluorescence intensity with increasing oxygen concentration. Thus, solid materials can be developed to measure the concentration of oxygen. Chemical reactions that either consume or produce oxygen can be determined. The fluorescence compound may be physically immobilized in a polymer such as silicone. On page 157 the reactions take place in cuvettes.

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Gentle (5,998,517) entitled "Composition for the Detection of Microorganisms in a Sample" teaches in the abstract, tris-4,7-diphenyl-1,10-phenanthroline ruthenium (II) dichloride pentahydrate to detect the growth of respiring microorganisms. In column 2 the BACTEC system uses silicone polymers as the sensor matrix because it transmits gases. See claims 11-19 in column 10.

The claims differ from each of Parker and Gentle in that they specify a control.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ a control in the method of each of Parker and Gentle because all the data obtained by the methods disclosed by the references are based upon some baseline, such as zero or 100% oxygen. To employ a control in a known assay for its known function with the expected result would have been obvious. Further, no result of the control is presently claimed. Employing computers in luminescence assays is old.

Claims 9-11, 13-15, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon.

The claims differ from Bacon in that they specify different ruthenium salts, the test sample is an enzyme, and a computer is employed in the assay.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ any known ruthenium salt known for being quenched by oxygen for the same function with the expected result as the specific ruthenium salt as specified by Bacon. No novelty is seen in the presently claimed compounds. Regarding the selection of the sample, no novelty is seen in employing the assay of Bacon for determining any desired analyte. Employing computers in assays is old.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 there are two sensor compositions but it is unclear if they are the same or different compositions. The term "signal" lacks parallelality, in 1(a) it is singular and in 1(b) it is plural. The term "sample" also lacks parallelality, in line 1 of claim 1 it is singular, in line 2 of 1(b) it is plural. Dependent claims 12 and 13 begin with an indefinite article. Claim 19 is directed to a computer system where "system" is indefinite as to what may be included with the computer.

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The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pitner (6,395,506) is a related patent.

Stitt (5,567,598) is a related patent.

Labuda (6,616,896) teaches oxygen monitoring.

Duebendorfer (6,538,735) teaches oxygen luminescence assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200